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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,890	11/21/2001	Susana Salceda	DEX-0287	1461

7590 07/26/2004

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,890	SALCEDA ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 7-8, drawn to a nucleic acid, cell, vector, classified in class 536, subclass 23.1 as well as class 435, subclasses 325 and 320.1. If this Group is elected, then the below summarized sequence election is also required.

II. Claims 6, 13, and 15, drawn to methods and kits for determining the presence of a breast specific nucleic acid or polypeptide, classified in class 435, subclasses 6 and 7.1 as well as class 422, subclass 61. If this Group is elected, then the below summarized sequence election is also required. If this Group is elected, then the below summarized specie election is also required.

III. Claim 9, drawn to a method for producing a polypeptide, classified in class 435, subclass 69.1. If this Group is elected, then the below summarized sequence election is also required.

IV. Claims 10-11, drawn to a polypeptide, classified in class 530, subclass 350. If this Group is elected, then the below summarized sequence election is also required.

V. Claim 12, drawn to an antibody, classified in class 530, subclass 387.1. If this Group is elected, then the below summarized sequence election is also required.

VI. Claim 14, drawn to a method for diagnosing and monitoring the presence and metastases of breast cancer in a patient, classified in class 436, subclass 64. If this Group is elected, then the below summarized sequence election is also required. If this Group is elected, then the below summarized specie election is also required.

VII. Claim 16, drawn to a method of treating a patient with breast cancer, classified in class 514, subclass 2. If this Group is elected, then the below summarized sequence election is also required.

VIII. Claim 17, drawn to a vaccine, classified in class 514, subclass 2. If this Group is elected, then the below summarized sequence election is also required. If this Group is elected, then the below summarized specie election is also required.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid/polypeptide sequences, the Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions of examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent

and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

Specie Election Requirement for Groups II, VI, and VIII:

This application contains claims directed to the following patentably distinct species of the claimed invention:

For Group II:

Specie A: determination of the presence of a nucleic acid (via hybridization)

Specie B: determination of the presence of a protein (via antibody binding)

For Group VI:

Specie C: a diagnostic and monitoring method involving a nucleic acid

Specie D: a diagnostic and monitoring method involving a protein

For Group VIII:

Specie E: a vaccine which includes a nucleic acid

Specie F: a vaccine which includes a protein

Applicant is required under 35 U.S.C. 121 to elect a single disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. This distinctness or independence of methods and vaccines involving a nucleic acid versus a protein is because they are directed to different chemical types featuring

different structures and functions as well as different method steps. The separate chemical types and method steps of these species are often separately characterized and published in literature, thus adding to the search burden if both species in each of Groups II, VI, and VIII were examined together. Also, processing that may connect two species in each of Groups II, VI, and VIII does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the two species in Groups II, VI, and VIII are independent and/or distinct invention types for restriction purposes.

Applicant is advised that a reply to this requirement must include an identification of the specie that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should an applicant traverse the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groupings [I, II (hybridization specie), III, VI (nucleic acid specie), VIII (nucleic acid specie)], [IV, VI (protein specie), and VIII (protein specie)], and [II (antibody-binding specie), V, and VII] are independent inventions because they are directed to different chemical or entity types regarding the critical limitations therein. For Groups I, II (hybridization specie), III, VI (nucleic acid specie), and VIII (nucleic acid specie); the critical feature is a nucleic acid. For Groups IV, VI (protein specie), and VIII (protein specie); the critical feature is a polypeptide. For Groups II (antibody-binding specie), V, and VII; the critical feature is an antibody. The completely separate chemical and entity types of the invention Groups are often separately characterized and published in literature, thus adding to the search burden if all Groups were examined together. Also, processing that may connect two Groups does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the three Groupings [I, II (hybridization specie), III, VI (nucleic acid specie), and VIII (nucleic acid specie)], [IV, VI (protein specie), and VIII (protein specie], [II (antibody-binding specie), V, and VII] are independent and/or distinct invention types for restriction purposes.

Inventions in Groups I, II (hybridization specie), III, VI (nucleic acid specie), and VIII (nucleic acid specie) are related as product and processes of use. The inventions can be shown to

be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group I may be utilized in distinct usages as needed in Group II (hybridization specie) for a method of determining the presence of a breast specific nucleic acid, in a method for producing a polypeptide as in Group III, in a method for diagnosing and monitoring the presence and metastases of breast cancer in a patient as in Group VI (nucleic acid specie), in a vaccine as in Group VIII (nucleic acid specie), or alternatively, in preparing T cells. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Inventions in Groups IV, VI (protein specie), and VIII (protein specie) are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group IV may be utilized in distinct usages as needed in Group VI (protein specie) for a method of diagnosing and monitoring the presence and metastases of breast cancer in a patient, in a vaccine as in Group VIII (protein specie), or alternatively, in cell growth inhibition studies. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Inventions in Groups II (antibody-binding specie), V, and VII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group V may be utilized in distinct usages as needed in Group II (antibody-binding specie) for a method of determining the presence of a breast specific nucleic acid, in a method of treating a patient with breast cancer as in Group VII, or alternatively, in preparing T cells. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

July 14, 2004